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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/716,960 | 11/21/2000 | Michael Brines | 10165-009-999 | 6595 |

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| EXAMINER |
|---|
| DEBERRY, REGINA M |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 08/26/2002 16

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/716,960 | BRINES ET AL. | |
| | Examiner | Art Unit | |
| | Regina M. DeBerry | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *7 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10* are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6,8,11* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

***Status of Application, Amendments and/or Claims***

The information disclosure statements filed 10 April 2001 (Paper No. 6), 16 October 2001 (Paper No. 8) and 05 March 2002 (Paper No. 11) were received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

The amendment filed 05 March 2002 (Paper No. 12) has been entered in full. Applicant's election with traverse of Group XIX (claims 1-6, 8,9) in Paper No. 12 is acknowledged. The traversal is on the grounds that the twenty restriction groups required by the Examiner do not represent independent, separately patentable inventions but, rather, are properly characterized as species of a single generic invention. Applicant states that the Groups are functionally identically in that the Groups recite methods of administering species of EPOs and EPO-like compounds which are capable of interacting with the EPO receptors of epithelial tights junctions, including the twenty designated species of compounds with this functional characteristic in common. Applicants state that the twenty groups represent a single species of a single invention. Applicants state that a search of all of the methods of the invention would not constitute an undue burden, since many of these species comprise structurally identical compounds and fall into a number of other groups.

Contrary to Applicant's assertion, the methods are drawn to administering different compositions such as analogs, multimers, EPO agonists, muteins and

congeners. The instant compositions may differ from erythropoietin both structurally and functionally. The term "EPO-receptor activity modulator" or "EPO-activated receptor modulator" can encompass various chemical compositions. A search of all of the methods of the invention would constitute an undue burden because of the diverse nature of the EPO compositions claimed. The requirement is still deemed proper and is therefore made FINAL. Claims 7 and 10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

The amendment filed 13 June 2002 (Paper No. 13) has been entered in full. Applicant's species election of neurodegenerative disease (claim 2) and central nervous system (claim 3) in Paper No. 15 is acknowledged. The traversal is on the grounds that it would not be a serious burden on the Examiner to search any relevant art to the diseases recited in claim 2 and the excitable tissue recited in claim 3 because the search for these elements should already been carried out in the search for prior art related to claim 1. Applicant states that a single search should, without undue burden, identify any relevant art pertaining to methods for prevention or treatment of neurodegenerative conditions recited in claim 2 or for the protection of excitable tissue of claim 3. This is found partly persuasive. The species election for excitable tissue is withdrawn. However, contrary to Applicant's assertion, the conditions in claim 2 would require search and consideration of diverse patient populations. A search is directed to references, which would render the invention obvious, as well as references directed to

anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter. A search for neurodegenerative conditions would not necessarily pick up the conditions listed in claim 2 or would, perhaps after an exhaustive search. The requirement is still deemed proper and is therefore made FINAL. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

### *Specification*

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to because of the following informalities: In the Brief Description of the Figures "FIG. 3A-B" should read "FIG. 3A-C" (page 7, line 9). Appropriate correction is required.

### *Claim Objections*

Claims 1,2, and 9 are objected to because of the following informalities: The instant claims encompass non-elected inventions and requires amendment to limit to elected invention. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it recites the limitation "said mammal". There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of improving cognitive function, improving memory, decreasing tissue necrosis in the brain due to trauma, decreasing tissue necrosis in the brain and heart due to hypoxia, decreasing neuronal injury due to excitotoxicity and delaying onset of encephalomyelitis symptoms in a mammal, comprising peripherally administering to said mammal, an amount of EPO that does not increase hemoglobin concentration or hematocrit in said mammal, wherein the mammal

has a neurodegenerative disease, does not reasonably provide enablement for the claims as cited. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant claims are drawn to the prevention or treatment of a neurodegenerative condition. Prevent means to hold back or keep from happening. The specification fails to teach how to prevent the onset of a neurodegenerative condition. Secondly, "neurodegenerative condition" is a very broad term. Neurodegenerative diseases are a varied assortment of central nervous system disorders characterized by gradual and progressive loss of neural tissue. The specification is not enabled for the prevention or treatment of the broad class of neurodegenerative conditions. Furthermore, the claims are only enabled for EPO amounts that do not increase hemoglobin concentration or hematocrit because increases in hemoglobin or hematocrit have been shown to cause detrimental effects in patients. Severe complications, such as hypertension, strokes or seizures can occur in patients receiving high doses of EPO over longer periods of time versus a bolus injection of EPO.

Due to the large quantity of experimentation necessary to prevent or treat neurodegenerative diseases, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention and the breadth of the claims which fail to recite limitations regarding specific neurodegenerative diseases and conditions, undue

experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

***Matter of Record***

Marsh teaches that recombinant human EPO treatment improves brain and cognitive function of anemic dialysis patients (Marsh *et al.* Kidney International, Vol. 39 pages 155-163, 1991, cited in IDS Paper # 6 BP). Grimm teaches that administering recombinant human erythropoietin in hemodialysis patients can improve brain function (Grimm *et al.* Kidney International, Vol. 38 (1990) pages 480-486, cited in IDS Paper # 6 BC). The art is made of record but not relied upon because both inventors teach long term administration of EPO that raises hemoglobin and hematocrit levels.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary L Kunz

RMD
August 19, 2002